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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,059	05/28/2002	Henry Yue	PF-0681 USN	4670

22428 7590 10/13/2005

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EXAMINER	
WEGERT, SANDRA L	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 10/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,059	YUE ET AL.	
	Examiner	Art Unit	
	Sandra Wegert	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

SDP

DETAILED ACTION

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The first claimed invention lacks a special technical feature because it fails to distinguish the claimed invention from the prior art (e.g., Toribara, et al, 1991, J. Clin. Invest., 88:1005-1013, refer to Accession No. AAA59875.1). The prior art discloses immunogenic fragments of SEQ ID NO: 1, for example. For this reason, none of the other claimed inventions can share a special technical feature with the first claimed invention.

Election/Restriction

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1, 2 and 15, drawn to a human transmembrane polypeptide and compositions comprising.

II. Claims 3-6, 8, 10 and 11, drawn to a DNA encoding a human transmembrane polypeptide, recombinant methods of making the polypeptide and host *cells* comprising the polynucleotide.

III. Claim 7, drawn to a transgenic organism comprising a human transmembrane polypeptide.

IV. Claim 9, drawn to an antibody which specifically binds to a human transmembrane polypeptide.

V. Claims 12-14, drawn to a method of detecting a polynucleotide using a hybridizing polynucleotide.

VI. Claim 16, drawn to a method of treating a disease by administering a human transmembrane polypeptide.

VII. Claims 17 and 20, drawn to a method for determining whether a compound is an agonist or antagonist of a human transmembrane polypeptide *ex vivo*.

VIII. Claims 18 and 21, drawn to an agonist or antagonist of a human transmembrane polypeptide.

IX. Claims 19 and 22, drawn to a method of treating a disease by administering an agonist or antagonist of a human transmembrane polypeptide.

X. Claim 23, drawn to a method of screening a compound for effectiveness in altering *expression* of a human transmembrane polypeptide.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventive Groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons: Groups I-IV and VIII are independent and distinct, each from the other, because their products possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged. The protein of Group I can be used to generate antibodies or can be used in methods of treatment.

The nucleic acids used in inventive Group II can be used to make a hybridization probe or can be used in gene therapy, as well as to produce the protein of Group I. The organism of Invention III can be used to study the physiological role of the polypeptide or can be used to produce the polypeptide. The antibody of Invention IV can be used to localize the protein of interest or can be administered for treatment. The ligand of Invention VIII can be used to localize the protein of interest or can be administered for treatment.

In addition, Groups I and II are related as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product, or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05 (f)). In the instant case the polypeptide can be prepared by materially different processes, such as by chemical synthesis, or obtained from nature using various isolation and purification protocols.

Invention I is unrelated to Inventions V, IX and X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the peptide of Group I is neither used in nor produced by the methods of Groups V, IX and X.

Invention I is related to Inventions VI and VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polypeptides of Group I can be used to

generate antibodies as well as to search for ligands, or for treatment.

Invention II is related to Inventions V and X as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polynucleotide can be used to produce the claimed polypeptide or can be used as a probe.

Invention II is unrelated to Inventions VI, VII and IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the DNA of Group II is neither used in nor produced by the methods of Inventions VI, VII and IX.

Invention III is unrelated to Inventions V and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the transgenic organism of Group III is neither used in nor produced by the methods of Group V and VII. In addition, Invention III is essentially unrelated to Inventions VI and IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the transgenic organism of Group III would not be administered the claimed polypeptide or ligand as treatment, because it already comprises the functioning polypeptide.

Invention III may be related to Invention X as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the organism can be used to produce the claimed polypeptide.

Invention IV is unrelated to Inventions V, VI, VII and X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibody of Group IV is neither used in nor produced by the methods of Groups V, VI, VII and X.

Invention IV may be related to Invention IX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the antibody can be used to produce the claimed polypeptide as well as used as an agonist or antagonist.

The methods of Inventions V, VI, VII, IX and X are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps, measured endpoints, probabilities of success, personnel and goals.

Invention VI is unrelated to Invention VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the agonist or antagonist would not be administered in a method of treatment involving application of the receptor itself.

Groups VII and VIII are related as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product, or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05 (f)). In the instant case the ligands can be identifies by materially different processes, such as by computer modeling.

Invention VIII is related to Invention IX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the ligand can be used for in situ localization of the receptor as well as used for treatment.

Invention VIII is unrelated to Invention X. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the receptor agonist or antagonist would not be used in a method of identifying DNA expression inhibitors.

Because these inventions are distinct for the reasons given above and the search required for each group is unique, and because each protein or nucleic acid requires a completely separate search, as well as by their different classifications, divergent subject matter and different search requirements, restriction for examination purposes as indicated is proper.

In response to this requirement, applicants must elect from Groups I through X. Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

Election/Restriction

Furthermore, restriction is required under 35 USC 121 and 372 as follows:

If applicant selects from Inventions I-X (above), <u>one</u> SEQ ID NO must also be selected to be considered responsive:

<u>A SEQ ID NO:</u>

1-58.

Each molecule (SEQ ID NO's 1-58) named above is independent and distinct, one from the other, because they have independent and distinct chemical structures (see, for example Table 2, instant Specification). Their searches are non-overlapping, resulting in an undue search burden.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not

apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW
5 October 2005

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER